Claim 54 (New) The medical device of claim 49 wherein the bioactive agent is selected from the group consisting of a growth factor, a cell attraction compound, an anticoagulant and combinations thereof.

Claim 55 (New) The medical device of claim 49 wherein the bioactive agent is VEGF.

REMARKS

The Office Action Summary indicates claims 1-38 are pending in the application with claims 24-38 being withdrawn from consideration. However, Applicants respectfully

submit that 39 claims were pending in this application. Thus, by this amendment, claims 24-39 have been canceled without prejudice or disclaimer. New claims 40-55 have been added. Support for new claim 40 can be found throughout the specification, for example, on page 3, lines 22-29, page 4, lines 4-5, page 5, lines 1-3 and lines 11-23, and page 16, lines 9-10. Support for new claim 41 can be found throughout the specification, for example, on page 10, lines 21-22. Support for new claims 42 and 51 can be found throughout the specification, for example, on page 7, lines 16-17 and page 17, lines 27-28. Support for new claims 43 and 52 can be found throughout the specification, for example, on page 8, lines 3-6. Support for new claims 44 and 53 can be found throughout the specification, for example, on page 24, lines 8-23. Support for new claims 45 and 54 can be found throughout the specification, for example, on page 8, lines 12-14 and page 22, line 23, to page 23, line 3. Support for new claims 46 and 55 can be found throughout the specification, for example, on page 22, lines 23-25. Support for new claim 47 can be found throughout the specification, for example, on page 22, lines 25-26. Support for new claim 48 can be found throughout the specification, for example, on page 24, lines 3-7. Support for new claim 49 can be found throughout the specification, for example, on page 3, lines 22-29, and on page 16, lines 10-17 and lines 19-23. Applicants respectfully assert that no new matter has been added and request reconsideration of all the claims currently pending in the application.

I. 35 U.S.C. §121

On page 2 of the current office action, the Examiner imposes a restriction Requirement under 35 U.S.C. §121 based on an assertion that the application contained three groups of claims. During a telephone call, Applicants' representative provisionally elected group I, claims 1-23 with traverse. While Applicants agree that the groups I, II

and III are independently patentable, they do not require additional searching by the Examiner and thus could be conveniently prosecuted together. However, in the interest of advancing the case, Applicants have confirmed the election of Group I and have canceled non-elected claims 24-39 without prejudice in view of the restriction.

II. Rejection under 35 U.S.C. §102 (a)

On page 3 of the Office Action, claims 1-2, and 4-21 are rejected under 35 U.S.C. §102 (a) as being anticipated by Li, et al. (U.S. Patent Number 6,231,879).

The Examiner states that Li, et al. disclose an implantable prosthesis (title) comprising a rigid material (col. 8, lines 16-17) with pores filled with hydrogel (col. 8, lines 5-15) and a structural protein (collagen, col. 6, lines 43-57).

With regard to claim 4, the Examiner notes that collagen is only coated in the pores.

With regard to claims 9-11 and 13, the Examiner cites column 1, lines 14-20 and column 10, lines 39-65.

With regard to claim 14, the Examiner cites column 7, lines 1-4.

With regard to claims 16 and 17, the Examiner notes that the material is an open celled foam having a network of pores (col. 5, lines 46-54).

With regard to claim 18, the Examiner notes that collagen is a nutrient.

With regard to claim 19, the Examiner contends that the reference teaches a device seeded with cells (col. 14, lines 1-2).

Finally, with regard to claims 20 and 21, the Examiner cites column 3-4, lines 64-5.

Applicants respectfully traverse the rejections.

Li et. al. teach methods of manufacturing implantable biocompatible cell encapsulation devices having a jacket made of a permeable biocompatible material and a foam core with cells dispersed in the foam pores. See abstract. The jacket allows passage of substances up to a predetermined size, but prevents the passage of larger substances, such as mammalian cells. See col. 4, lines 35-36 and claim 1. Preferably, the devices of this invention are immunoisolatory, meaning that when the devices are implanted into a mammalian host, the deleterious effects of the host's immune system on the cells within the cores is minimized so that the devices can function for extended periods of time in vivo. Col. 5, lines 4-9. To be immunoisolatory, the surrounding or peripheral region of the device is constructed to protect the cells with a physical barrier sufficient to prevent detrimental immunological contact between the encapsulated (isolated) cells and the host's immune system, and to prevent harmful substances of the host's body from entering the core of the device. Col. 5, lines 9-16. Any suitable thermoplastic or thermoplastic elastomeric foam scaffold material, preferably polyvinyl alcohol (PVA) sponges, may be preformed for insertion into a pre-fabricated jacket. Col. 8, lines 3-6. PVA sponges are water-insoluble foams formed by the reaction of aerated Poly(vinyl alcohol) solution with formaldehyde vapor as the crosslinker, and the hydroxyl groups on the PVA covalently crosslink with the aldehyde groups to form the polymer network, which are flexible and elastic when wetted and semi-rigid when dried. Col. 8, lines 12-17. The foam scaffold may also be pre-formed and then coated with a cell impermeable jacket. See col. 8, lines 47-48. Any suitable method of sealing the devices may be used, including the employment of polymer adhesives and/or well-known techniques such as crimping, knotting and heat sealing. Col. 9, lines 17-20. If dry sealing

is done, a substantially non-porous fitting member is provided which is attached to the membrane encapsulation device with a secure dry seal and the cell-containing solution can be introduced through such fitting member. Col. 9, lines 20-25. Subsequent to filling, the device is sealed by closing the opening in the non-porous fitting. See col. 9, lines 25-27.

The cell encapsulating device of Li et. al. is a device for holding cells. As noted by the above cited passages, the device is sealed with the cells inside, and the jacket of the sealed device prevents the passage of cells and other materials in or out. In addition to the foams being flexible and elastic when wet, the pores are not filled with hydrogels, as Li et. al. specifically distinguish itself from prior art uses of hydrogels. See col. 2, lines 59-60. Thus, contrary to the Examiner's assertions regarding the recited passages of Li et. al. (title, col. 6, lines 43-57, col. 8, lines 5-15 and col. 8, lines 16-17), Li et. al. do not teach an implantable prosthesis comprising a rigid material with pores filled with hydrogel and a structural protein.

Claim 1, on the other hand, is related to an implantable prosthesis comprising a rigid material with pores, with a filler comprising a hydrogel, a structural protein, a bioactive agent, or mixtures thereof, located within the pores.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all

claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. Applicants respectfully submit that Li et. al. do not teach every element of claim 1, as noted above, and therefore fails to anticipate claim 1.

Dependent claims 2, and 4-21, which are dependent from independent claim 1, were also rejected under 35 U.S.C. §102(a) as being anticipated by Li et. al.. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2, and 4-21 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 1-2, and 4-21 under 35 U.S.C. §102 (a) as being anticipated by Li, et al.

III. Rejection under 35 U.S.C. § 103(a)

On page 4 of the Office Action, claims 1-3, 5-15, and 18-23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over MacGregor (U.S. Patent Number 4,936,317) in view of Carlyle, et al. (International Publication Number WO 01/41825).

The Examiner states that MacGregor discloses a heart valve (col. 3-6) including a rigid polymer occluder with a porous surface. The Examiner admits that MacGregor does not disclose a filler consisting of mixtures of hydrogel, structural protein, and bioactive agents, but cites Carlyle, et al., which discloses a coating for heart valves occluders consisting of mixtures of hydrogel, structural protein, and bioactive agents for the

purpose of causing cell adhesion to the surface in support of the rejection. In view of this, the Examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the occluder of MacGregor with the coating material of Carlyle, et al. (thereby filling the pores of the occluder) in order to promote cell adhesion to the surface.

With regard to claim 3, the Examiner notes that the surface in figures of Carlyle, et al. appears smooth and page 3 states that it is suitable for contact with the patient's bodily fluids.

With regard to claim 5, the Examiner cites page 12, 2nd paragraph of Carlyle, et al.

With regard to claims 6 and 7, see page7, 2nd paragraph of Carlyle, et al.

With regard to claim 8, the Examiner cites page 22, 2nd paragraph of Carlyle, et al.

With regard to claims 9-13, the Examiner cites page 7, 2nd paragraph of Carlyle, et al.

With regard to claim 15, the Examiner notes that both Carlyle, et al and MacGregor mention the use of anticoagulants. However, though the Examiner notes that the filler as disclosed does not include anticoagulant, he notes that it is well known in the art of hydrogels to include anticoagulants therein to prevent clotting, and thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to include anticoagulant in the hydrogel of Carlyle in order to prevent clotting.

With regard to claim 18, the Examiners notes that collagen is a nutrient of Carlyle, et al.

With regard to claim 19, the Examiner cites page 25, 2nd paragraph of Carlyle, et al.

Finally, with regard to claims 20-21, the Examiner cites page 12, 1st paragraph of Carlyle, et al.

Applicants respectfully traverse the rejections.

Applicants have attached a Declaration under 37 C.F.R § 1.131 of Yi-Ren Woo, a co-inventor of the present application. As stated in the Declaration, Applicants were in possession of the invention before the publication date of Carlyle WO01/41825. Applicants believe that Carlyle becomes a reference due to the publication date under 35 USC 102(a). Since Applicants possessed the invention prior to the publication of Carlyle, Carlyle is not a proper 102(a) reference. Since Carlyle et al is not a proper reference, the combination of MacGregor with Carlyle et al. does not render Applicants' claimed invention obvious, as even the Examiner admits that MacGregor does not teach or motivates the subject matter of claim 1.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicants respectfully traverse the rejection since the prior art fails to disclose all the claim limitations and there would be no motivation to combine the references as proposed by the Examiner.

Dependent claims 2-3, 5-15 and 18-23, which are dependent from independent claim 1, were also rejected under 35 U.S.C. §103(a) as being unpatentable over MacGregor in view of Carlyle et. al.. Applicants believes that these rejections are moot

in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2-3, 5-15 and 18-23 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 1-3, 5-15, and 18-23 are under 35 U.S.C. § 103(a) as being unpatentable over MacGregor in view of Carlyle, et al.

IV. Conclusion

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at (952) 253-4134.

Respectfully submitted,

Altera Law Group, LLC
Customer No. 22865

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By: Hallie A Finucane
Hallie A. Finucane
Reg. No. 33,172
HAF/mar